IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

UNITED STATES OF AMERICA, Plaintiff, v. PFIZER, INC., Defendant.	Civil Action No.

COMPLAINT

The United States of America, by authority of the Attorney General of the United States and through the undersigned attorneys, acting at the request of the Administrator of the United States Environmental Protection Agency ("EPA"), files this complaint and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action brought pursuant to Section 113 of the Clean Air Act ("Act"), 42 U.S.C. § 7413, to obtain civil penalties against Pfizer, Inc. ("Pfizer") for violations of Section 112 of the Act, 42 U.S.C. § 7412, and regulations promulgated thereunder, codified at 40 C.F.R. Part 63, Subpart H and Subpart GGG, pertaining to leak detection and repair requirements for hazardous air pollutants emitted from pharmaceutical manufacturing facilities.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action, pursuant to 28 U.S.C. §§ 1331, 1345 and 1355, and Section 113(b) of the Act, 42 U.S.C. § 7413(b).

3. This Court has personal jurisdiction over Pfizer, which is a corporation doing business in the State of Connecticut, pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b).

4. Venue lies in the District of Connecticut pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 28 U.S.C. §§ 1391(b) and (c), and 1395(a), because Pfizer is found in and conducts business in this District and because the alleged violations occurred within this District.

NOTICE

5. Notice of commencement of this action has been given to the State of Connecticut, specifically, the Connecticut Department of Environmental Protection, as required by Section 113(b) of the Act, 42 U.S.C. § 7413(b).

DEFENDANT

6. Pfizer is a Delaware corporation with its corporate headquarters in New York, New York.

7. At all times pertinent to this action, Pfizer owned and operated a pharmaceutical manufacturing facility located at 445 Eastern Point Road in Groton, Connecticut ("Facility").

8. Pfizer is a "person" within the meaning of Section 302(e) of the Act, 42 U.S.C. § 7602(e).

STATUTORY AND REGULATORY BACKGROUND

9. Pursuant to Section 112(d), (f) and (h) of the Act, 42 U.S.C. § 7412(d), (f) and (h), EPA is required to promulgate regulations that establish national emission standards and/or work practice and equipment standards applicable to major sources of hazardous air pollutants, which are listed for regulation under Section 112(b) of the Act, 42 U.S.C. § 7412(b).

10. Pursuant to Section 112 of the Act, 42 U.S.C. § 7412, EPA promulgated the "National Emission Standards for Hazardous Air Pollutants Pharmaceutical Production," codified at 40 C.F.R. Part 63, Subpart GGG ("Subpart GGG"). Subpart GGG applies to all "affected sources," which includes, but is not limited to, existing major sources of hazardous air pollutants that manufacture pharmaceutical products, as defined in 40 C.F.R. § 63.1250(a).

11. To control or reduce emissions of hazardous air pollutants in conformance with Section 112 of the Act, Subpart GGG establishes standards for several types of emissions points from pharmaceutical manufacturing operations, including standards for equipment leaks, referred to as "leak detection and repair" ("LDAR"), and set forth at 40 C.F.R. § 63.1255.

12. The LDAR program in 40 C.F.R. § 63.1255 sets forth various equipment/work practice, testing and recordkeeping requirements, *inter alia,* to ensure that any leaks of air pollutants from equipment used in the manufacture of pharmaceutical products are timely detected and repaired.

13. As set forth in 40 C.F.R. § 63.1255(a), the LDAR requirements apply to numerous process equipment within an affected source that is intended to operate using a hazardous air pollutant in the manufacture of pharmaceutical products for 300 hours or more during the calendar year.

14. Section 112(i) of the Act, 42 U.S.C. § 7412(i), prohibits any person from operating any source in violation of any emission standard, limitation, or regulation promulgated under Section 112 and applicable to such source, and further requires EPA to establish compliance dates for existing sources no later than 3 years after the effective date of such standard, limitation, or regulation.

15. Under 40 C.F.R. § 63.1250(f)(1), Subpart GGG sets forth a compliance date of October 21, 2002, for any owner or operator of an existing source to which Subpart GGG applies.

16. Section 113(b) of the Act, 42 U.S.C. § 7413(b), authorizes EPA to commence a civil action against any person that is an owner or operator of an affected source or a major stationary source who violates, *inter alia*, any regulations and standards imposed pursuant to Section 112 of the Act, and obtain appropriate relief, which includes civil penalties of up to $25,000 per day for each violation. The Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, as amended by the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, and EPA implementing regulations, codified at 40 C.F.R. Part 19, increased these statutory maximum penalties to up to $27,500 per day for each violation that occurred after January 31, 1997, and up to $32,500 per day for each violation that occurred after March 15, 2004.

GENERAL ALLEGATIONS

17. At all times pertinent to this action, the Facility was an "existing source," and a "major source" of "hazardous air pollutants" within the meaning of Section 112(a) of the Act, 42 U.S.C. § 7412(a).

18. At all times pertinent to this action, Pfizer was an "owner" and an "operator" of the Facility within the meaning of Section 112(a) of the Act, 42 U.S.C. § 7412(a).

19. At all times pertinent to this action, the Facility was an "affected source" that engaged in pharmaceutical manufacturing operations within the meaning of 40 C.F.R. §§ 63.1250(a) and 63.1251, and thus was subject to the requirements in Subpart GGG.

20. At all times pertinent to this action, the batch product-process equipment at the Facility was subject to the LDAR requirements in 40 C.F.R.§ 63.1255.

21. The LDAR program requirements in Subpart GGG refer to and incorporate many of the requirements of the "National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks" at 40 C.F.R. Part 63, Subpart H ("Subpart H") to which the Facility was also subject at all times pertinent to this action.

22. Facilities subject to Subpart GGG can demonstrate compliance with LDAR requirements by using one of two procedures, namely, by pressure testing as described in Subpart H, 40 C.F.R. § 63.180(f) and (g), or by Method 21 of 40 C.F.R. Part 60, Appendix A. At all times pertinent to this action, Pfizer elected to use pressure testing as its sole method for determining compliance with LDAR requirements from its batch process pharmaceutical manufacturing operations at the Facility.

FIRST CLAIM FOR RELIEF

Failure to Timely Repair and Re-Test Leaking Equipment

23. Paragraphs 1-22 are realleged and incorporated herein by reference.

24. For facilities that elect to use pressure testing to demonstrate compliance with LDAR requirements, Subpart GGG requires, by reference to Subpart H, that owners or operators of affected sources repair leaking batch product-process equipment that exceeds the standards set forth in 40 C.F.R. § 63.178(b)(3), and re-test it before start-up. 40 C.F.R. § 63.1255(b)(4)(iv); and 40 C.F.R. § 63.178(b)(4).

25. On numerous occasions from at least November 2002 through December 2005, Pfizer failed to timely repair leaks that were detected at its Facility and/or re-test batch

product-process equipment before subsequent start-up at its Facility in conformance with the requirements of 40 C.F.R. §§ 63.1255(b)(4)(iv) and 63.178(b)(4).

26. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, Pfizer is liable for civil penalties of up to $27,500 per day for each violation of 40 C.F.R. §§ 63.1255(b)(4)(iv) and 63.178(b)(4) that occurred from January 31, 1997 through March 15, 2004, and up to $32,500 per day for each violation of 40 C.F.R. §§ 63.1255(b)(4)(iv) and 63.178(b)(4) that occurred after March 15, 2004.

SECOND CLAIM FOR RELIEF

Failure to Properly Conduct Pressurized Gas Tests to Detect Leaks

27. Paragraphs 1-26 are realleged and incorporated herein by reference.

28. Subpart GGG requires, by reference to Subpart H, that owners or operators of affected sources, who elect to use pressure testing of batch product-process equipment to demonstrate compliance with LDAR requirements, use either the procedures specified in 40 C.F.R. § 63.180(f) for a gas test, or the procedures set forth in 40 C.F.R. § 63.180(g) for a liquid test. 40 C.F.R. § 63.1255(b)(4)(iv) and (v), and 40 C.F.R. § 63.178(b)(2).

29. As set forth in 40 C.F.R § 63.180(f), Subpart H establishes, in pertinent part, required methods and procedures to test batch product-process equipment for leaks using a pressurized gas.

30. On numerous occasions from at least October 2002 through December 2005, Pfizer failed to properly conduct pressurized gas tests of batch product-process equipment at its Facility in conformance with the requirements of 40 C.F.R. §§ 63.1255(b)(4)(iv) and (v), and 40 C.F.R. § 63.180(f), to assess if there were any leaks from such equipment that required repair.

31. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, Pfizer is liable for civil penalties of up to $27,500 per day for each violation of 40 C.F.R. §§ 63.1255(b)(4)(iv) and (v), and 40 C.F.R. § 63.180(f) that occurred from January 31, 1997 through March 15, 2004, and up to $32,500 per day for each violation of 40 C.F.R. §§ 63.1255(b)(4)(iv) and (v), and 40 C.F.R. § 63.180(f) that occurred after March 15, 2004.

THIRD CLAIM FOR RELIEF

Failure to Properly Conduct Pressurized Liquid Tests to Detect Leaks

32. Paragraphs 1-31 are realleged and incorporated herein by reference.

33. As set forth in 40 C.F.R § 63.180(g), Subpart H establishes, in pertinent part, required methods and procedures to test batch product-process equipment for leaks using a pressurized liquid.

34. On numerous occasions from at least December 2002 through May 2004, Pfizer failed to properly conduct pressurized liquid tests of batch product-process equipment at its Facility in conformance with the requirements of 40 C.F.R. §§ 63.1255(b)(4)(iv) and (v), and 40 C.F.R. § 63.180(g), to assess if there were any leaks from such equipment that required repair.

35. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, Pfizer is liable for civil penalties of up to $27,500 per day for each violation of 40 C.F.R. §§ 63.1255(b)(4)(iv) and (v), and 40 C.F.R. § 63.180(g) that occurred from January 31, 1997 through March 15, 2004, and up to $32,500 per day for each violation of 40 C.F.R. §§ 63.1255(b)(4)(iv) and (v), and 40 C.F.R. § 63.180(g) that occurred after March 15, 2004.

FOURTH CLAIM FOR RELIEF

Failure to Seal Open-Ended Valves or Lines

36. Paragraphs 1-35 are realleged and incorporated herein by reference.

37. 40 C.F.R. § 63.1255(d) of Subpart GGG requires, in pertinent part, that owners or operators of affected sources equip each open-ended valve or line with a cap, blind flange, plug, or second valve which seals the open end.

38. On or about May 25, 2005, there were at least two instances of open-ended lines at the Facility in which neither open-ended line was equipped with a cap, blind flange, plug, or second valve which sealed the open end as required by 40 C.F.R. § 63.1255(d).

39. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, Pfizer is liable for civil penalties of up to $32,500 per day for each violation of 40 C.F.R. § 63.1255(d).

FIFTH CLAIM FOR RELIEF

Failure to Properly Document Test Procedures and Test Results

40. Paragraphs 1-39 are realleged and incorporated herein by reference.

41. 40 C.F.R. § 63.1255(g)(5) of Subpart GGG requires that an owner or operator of an affected source, who elects to determine compliance using pressure testing, keep records pertaining to pressure tests, including, but not limited to, the dates of each pressure test, the test pressure, and the pressure drop observed during the test.

42. On numerous occasions from at least December 2002 through May 2004, the pressure test records kept by Pfizer for the Facility failed to include one or more of the following pieces of information: date of the pressure test, test pressure, and/or pressure drop observed during the test, as required by 40 C.F.R. § 63.1255(g)(5).

43. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, Pfizer is liable for civil penalties of up to $27,500 per day for each violation of 40 C.F.R. § 63.1255(g) that occurred from January 31, 1997 through March 15, 2004, and up to $32,500 per day for each violation of 40 C.F.R. § 63.1255(g) that occurred after March 15, 2004.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the United States of America, prays that this Court:

1. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, assess civil penalties against Pfizer of up to $27,500 per day for each violation of Subpart GGG, and by reference Subpart H, that occurred from January 31, 1997 through March 15, 2004, and up to $32,500 per day for each violation of Subpart GGG, and by reference Subpart H, that occurred after March 15, 2004; and

2. Grant the United States such other relief as this Court deems appropriate.

Respectfully submitted,

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Complaint in *United States v. Pfizer, Inc.*, (D. Conn.), relating to Pfizer's former pharmaceutical manufacturing facility in Groton, Connecticut.

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